DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

M2494n

PURGED

February 4, 1999

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 15

James A. Kooiker
Kooiker Calves
West 2775 Highway AZ
Rio, Wisconsin 58960

Dear Mr. Kooiker:

A recent investigation of your calf-raising operation located at Rio, WI, conducted by our investigator confirmed that you offered an animal for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act, and that you caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about March 23, 1998, you sold a calf, identified by the United States Department of Agriculture, Food Safety and Inspection Service as case number 98-0267-WI, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of 0.31 parts per million (ppm) gentamicin in the kidney. A tolerance has not been established for residues of gentamicin in the edible tissues of calves. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially

harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species; for assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

You are adulterating the drug [redacted] (brand of gentamicin sulfate) within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug in calves without following the veterinarian's directions for use and the proper withdrawal period cause the drug to be unsafe to use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for ensuring that your overall operation and the food you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step being taken, that has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address indicated on the letterhead.

Sincerely,

James I. Roberts
Acting Director
Minneapolis District

RPS/ccl

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